

Amendment filed November 22, 2010

Reply to OA dated July 22, 2010

**REMARKS**

Claims 1-8, 10 and 12-20 are pending in this application, with claims 13-15, 18 and 19 withdrawn from consideration. Claims 1, 3 and 10 are amended herein. Upon entry of this amendment, claims 1-8, 10 and 12-20 will be pending, with claims 13-15, 18 and 19 withdrawn from consideration. Entry of this amendment and reconsideration of the rejections are respectfully requested.

No new matter has been introduced by this Amendment. Support for the amendments to the claims is discussed below.

**Regarding the Information Disclosure Statement**

The Examiner states that the Information Disclosure Statement filed on November 27, 2006, has not been considered, because it is not properly labeled as corresponding to the present application, and because the references do not appear to be relevant.

However, Applicants did **not** file an Information Disclosure Statement on November 27, 2006.

Applicant has reviewed the IDS document referred to by the Examiner in the PAIR system, and although the serial number is listed as 10/517,324, **none of the other data in this document corresponds to the present application**. This IDS was signed by Neil Greenblum of Greenblum and Bernstein, PLC. This IDS was therefore **from another application** and Mr. Greenblum apparently mistakenly placed the present serial number on the document.

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**The disclosure is objected to for containing sequence rule non-compliant subject matter.**

**See pages 5-8 and Figures 1A, 2A, 3A, 3B, 4A, and 4B, which contain nucleotide sequences that are at least 10 nucleotides in length, wherein the sequences are not accompanied by appropriate SEQ ID Nos. (Office action p. 3)**

The objection is overcome by the amendments to the drawings and the specification. All occurrences of nucleotide sequences requiring sequence identifiers have been labeled with the sequence identifiers.

**Claims 1 and 3 are objected to because of informalities. (Office action p. 3)**

The objection is overcome by the amendments to the claims. The claims have been amended incorporating the Examiner's suggested amendments.

**Claims 1-8, 10, 12, and 16-17 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for particularly point out and distinctly claim the subject matter which applicant regards as the invention. (Office action p.5)**

The rejection is overcome by the amendments to the claims.

The Examiner states that "each of said promoters" in claim 1 is without antecedent basis. Claim 1 has been amended in part as follows: "wherein each dsDNA comprises a nucleotide segment wherein both strands comprise two polymerase III-promoters placed in opposite orientation at the two ends, between the two promoters is a stretch wherein both strands contiguously encode a promoter." The recitation of the two polymerase III-promoters provides antecedent basis for the later recitation of "each of said promoters."

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The Examiner refers to “said dsRAN-encoding sequence” in claim 3. This was a typographical error and has been amended to --said dsRNA-encoding sequence--, for which there is antecedent basis.

The Examiner refers to the recitation in the last line of claim 3. This has been amended as follows: “randomized in between from between 4 nucleotide positions and all nucleotide positions along the length of the encoded dsRNA.” That is, the randomization occurs in nucleotide positions along the length of the encoded dsRNA, where the number of randomized positions is between 4 of the positions and all of the positions.

Claim 10 has been amended to delete the parenthetical phrase “(or mRNA).” One of skill in the art would understand that mRNA is part of the source RNA.

**Claims 1-8, 10, 12, and 16-17 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. (Office action p. 6)**

The rejection of the claims under 35 U.S.C. 112, first paragraph, is respectfully traversed, and reconsideration is requested.

The Examiner states that the claims are drawn to a DNA library with dsDNAs having “a dsDNA-encoding sequence of 10-30 base pairs.” The Examiner then refers to page 11 of the specification, disclosing siRNA of 19-21 base pairs, and states that the specification implies that dsRNA shorter than about 19 base pairs is not known to mediate RNA interference in cells. The Examiner states that the specification is silent as to whether a dsRNA of 10 base pairs has practical utility.

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The Examiner states: "In light of the above, the instant specification does not clearly allow persons of ordinary skill in the art to recognize that the inventors invented the genus claimed in the instant case."

In traversing the rejection, Applicant submits that claim 1 is directed to "A DNA-library for production of double stranded RNA-molecules ..." That is, the claim is directed to the **library of dsDNA molecules**. This scope of this library is fully described in the specification.

The use of dsRNA in RNA interference is only **one possible use** of the dsRNAs made using the dsDNA library. The fact that dsRNAs shorter than 19 base pairs are not **useful** in **one** particular application does not in any way bear on the issue of whether the dsDNA library itself is adequately described in the specification.

The Examiner has presented no arguments indicating that the scope of the dsDNA library of claim 1 is not fully described in the specification. The Examiner's remarks about "a representative number of species" are inappropriate. The dsDNA library is defined by the promoter sequence, the terminator sequence, and the dsRNA-encoding sequence in the dsDNA molecules. The Examiner appears to be focusing on the dsRNA-encoding sequence portion, but this is generally a "randomized" sequence of 10-30 base pairs. That is, all of these sequences are present, as is conventional in a library. This is fully described in the specification.

Reconsideration of the rejection is therefore respectfully requested.

**Claims 1-8, 10, 12, and 16-17 are rejected under 35 U.S.C. §102(e) as being anticipated by Li et al. (US 2004/0146858 A1). (Office action p. 8)**

The rejection over Li et al. is respectfully traversed.

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Applicant notes note that Li et al. '858 was filed on July 23, 2003, and claims priority of provisional application 60/398,915 filed on July 24, 2002.

The present application is a 371 National stage application of PCT/SE2003/001077, filed on **June 23, 2003**. Therefore, the application published as Li et al. '858 US application is **not prior art unless it is supported by Li's provisional application**.

However: 1) the Examiner has not provided a copy of Li's provisional application; and 2) the Examiner has not made any reference to the content of Li's provisional application.

Applicant does not have a copy of Li's provisional application 60/398,915 filed on July 24, 2002.

Since Li '858 is not prior art for this application unless supported by Li's provisional application 60/398,915, Applicant respectfully submits that the rejection, as stated, is improper. If Li's provisional application 60/398,915 is to be relied on, a copy of this application should be provided, and the content of this application should be specifically cited in the rejection.

If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact the applicants' undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

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In the event that this paper is not timely filed, the applicants respectfully petition for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

KRATZ, QUINTOS & HANSON, LLP



Daniel A. Geselowitz, Ph.D.

Agent for Applicants

Reg. No. 42,573

DAG/xl

Atty. Docket No. **040679**

Suite 400

1420 K Street, N.W.

Washington, D.C. 20005

(202) 659-2930



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PATENT & TRADEMARK OFFICE

Enclosures: Replacement Sheets of Drawing (Figs. 1A, B; 2A, B; 3A, B; 4A, B)  
Petition for Extension of Time

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